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Filed: July 17, 2001
Response t Restriction Requirement

Remarks

In the Office Action mailed November 29, 2002, the claims were divided into 30 groups.

Group I, claims 1-4, 30-31, 36, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a compound which inhibits the effect of aldosterone;

Group II, claims 1-2, 5-6, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a chymase inhibitor;

Group III, claims 1-2, 7-8, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a cathepsin inhibitor;

Group IV, claims 1-2, 9-10, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a receptor blocker;

Group V, claims 1-2, 11-13, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an imidazoline receptor antagonist;

Group VI, claims 1-2, 14, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of clonidine;

Group VII, claims 1-2, 15-16, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a peripherally acting receptor antagonist.

Group VIII, claims 1-2, 17-18, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a ganglion blocking agent.

Group IX, claims 1-2, 19-21, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an opiate;

Group X, claims 1-2, 19, 22, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of scopolamine;

Group XI, claims 1-2, 23-24, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of an endothelin receptor antagonist;

Group XII, claims 1-2, 25-26, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a xanthine oxidase inhibitor;

Group XIII, claims 1-2, 27, 30-31, 36, 41, drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of erythropoietin;

Group XIV, claims 28, 37, 46-47, drawn to a method of treating weight loss due to underlying disease, by electrically stimulating the patient's muscles;

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Group XV, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of an agent which reduces sympathetic nervous activity;

Group XVI, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of aldosterone antagonist;

Group XVII, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of chymase inhibitor;

Group XVIII, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of cathepsin inhibitor;

Group XIX, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of imidazoline antagonist;

Group XX, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of ganglion blocking agent;

Group XXI, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of opiate;

Group XXII, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of digitalis alkoid;

Group XXIII, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of scopolamine;

Group XXIV, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of growth hormone;

Group XXV, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of insulin-like growth factor;
Group XXVI, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of endothelin antagonist;
Group XXVII, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of TNF antagonist;
Group XXVIII, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of xanthine oxidase inhibitor;
Group XXIX, claims 38 and 39, drawn to a method of enhancing exercise performance in a healthy patient by administering an effective amount of erythropoietin;
Group XXX, claim 40, drawn to a method of enhancing exercise performance in a healthy patient, by electrically stimulating the patient's muscles.

In the response to the restriction requirement filed on January 29, 2003, Applicants amended claim 1, cancelled the remaining claims and elected prosecution of the single claim. The Examiner asserts in the Office Action mailed April 17, 2003 that this was non-responsive. Applicants respectfully maintain that a single group was elected for prosecution in the response filed January 29, 2003. As this was deemed unacceptable by the Examiner, Applicants elect Group I drawn to a method of treating weight loss due to underlying disease, by administering to the patient an effective amount of a compound which inhibits the effect of aldosterone, with traverse. Applicants respectfully request reconsideration of this restriction requirement because it is not consistent with the guidelines for restriction practice set forth in the Examiner's own MANUAL OF PATENT

EXAMINING PROCEDURE. If the Examiner does not reconsider this restriction requirement in view of the guidelines, Applicants will be obliged to hereby petition the Commissioner for supervisory review of this restriction requirement.

THE PRESENT RESTRICTION REQUIREMENT IS TOTALLY IMPROPER

The restriction requirement is improper. At most, the claims should have been divided into the following groups:

Group I, claims 1-27, 29-31, 35, 36 and 41 drawn to a method of treating weight loss by administration of an effective amount of an agent which reduces sympathetic nervous system activity.

Group II, claims 28, 37, 46 and 47 drawn to a method of treating weight loss by electrically stimulating the patient's muscles.

Group III, claims 38-40, drawn to a method of enhancing exercise performance.

The groups share a common disorder: weight loss, and a group of agents all acting by the same mechanism, in the case of group I, claim 1, an agent which reduces sympathetic nervous system activity.

THE CLAIMED METHODS ARE RELATED

The MPEP states that species, "while usually independent, may be related under the particular disclosure. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP 806.05- 806.05(i)." (MPEP 806.04(b))

The relationship between species is disclosed. Compounds that inhibit SNS activity are disclosed on page 1, lines 7-13 and page 4, lines 1-8. "Current Patent and Trademark Office policy precludes restriction, even in the case of multiple species, unless the two groups of claims are patentable over each other (i.e., neither is obvious in the light of the other) (Chisum 4:12.03).

THE GENERIC CLAIMS ARE PROPER

Applicants note that claims 3-27 are limited to species of compounds to decrease SNS activity. Thus, only these claims are specific claims as defined above. Accordingly, Applicants note that, with respect to these species, claims 1, 2, 35, 36, 39 and 41 are generic.

The claims are directed to a method of treating weight loss or a method for enhancing exercise performance by decreasing sympathetic nervous system activity. The common technical feature of this invention is that the claimed compounds all decrease sympathetic nervous system activity which is fundamental to this invention. These compounds are known in the art as having anti-sympathetic actions. For example, they are used clinically as anti-hypertensive medications to reduce blood pressure.

The compounds to treat cachexia share the common technical feature of decreasing SNS and thus constitute a proper Markush group. "Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility" *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). These compounds are defined in a proper genus as

listed in the Markush groups contained in generic claims 1,2, 35, 36, 39 and 41. Species claims follow in the dependent claims, for example claims 3-27. Reference is made to *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925) wherein alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. This decision permits claiming a genus expressed as a group consisting of certain specified materials is fields such as pharmacy and pharmacology.

In an election of species, only the elected species is initially examined. Once this claim is determined to be allowable, the examiner must search the remaining species. The claimed methods are related because they all have (1) a common mechanism of action; (2) a common target; and (3) a common result, i.e., "treating weight loss due to underlying disease by administering a compound".

THE ELECTION OF SPECIES BETWEEN DISEASES IS IMPROPER

The Office Action also required election of a species from among the diseases in claims 29 and 46. In response, applicants elect for examination of cancer, with traverse.

Applicants initially note that the requirement for election of species appears to be improperly drawn. The disease species are not embodiments reciting mutually exclusive characteristics as required to make a proper election of species requirement. In this regard applicants refer to MPEP § 806.04(f) which states in relevant part:

The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which *under the disclosure* are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. (emphasis added)

Thus, this test requires that the subject matter of claims have mutually exclusive subject matter, *as disclosed in the specification*, for restriction to different species. The diseases are disclosed as a group on page 1, lines 7-13 and page 4, lines 1-8 of the specification, with the common feature of all causing cachexia. They do not have any mutually exclusive subject matter as disclosed. Election of species for a specific disease is not proper.

SUMMARY

The present restriction requirement is improper. The claims should be divided into at most 3 groups with an election of species for the compound to be administered. There should be no election of species for a disease because the subject of the treatment method is the weight loss itself. The underlying disease causing the weight loss is irrelevant. Applicants request rejoinder of the claims as described above with an election of species for the compound to be administered.

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Favorable consideration of claims claim 1-27, 29-31, 35, 36 is earnestly solicited.

Respectfully submitted,

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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, May 7, 2003, to the Commissioner for Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

Aisha Wyatt

Date: May 7, 2003

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